

# Autologous Myoblast and Muscle Cell Injection, Medical 262

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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.

## **Description & Definitions:**

Autologous Myoblast and Muscle Cell Injection is a procedure to biopsy a muscle and cultured before injecting into to another muscle to assist with regenerating damaged tissue.

## Criteria:

Autologous Myoblast and Muscle Cell Injection is considered **not medically necessary** for any indication.

## Document History:

**Revised Dates:** 

- 2020: January
- 2016: January
- 2015: March, August, September
- 2014: October
- 2013: January, March, April, May, July
- 2012: April, November
- 2010: March, April, August
- 2009: January, April

Reviewed Dates:

- 2025: February
- 2024: February
- 2023: February
- 2022: February

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- 2021: February
- 2020: February
- 2018: November
- 2017: December
- 2014: April
- 2011: April
- 2010: July

Effective Date:

• August 2008

# Coding: Medically necessary with criteria: Coding Description None None Considered Not Medically Necessary: Coding Coding Description 53899 Unlisted procedure, urinary system.

U.S. Food and Drug Administration (FDA) - approved only products only.

The preceding codes are included above for informational purposes only and may not be all inclusive. Additionally, inclusion or exclusion of a treatment, procedure, or device code(s) does not constitute or imply member coverage or provider reimbursement.

# Special Notes: \*

- Coverage:
  - See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.
- Application to products:
  - Policy is applicable to Sentara Health Plan Virginia Medicaid products.
- Authorization requirements:
  - Pre-certification by the Plan is required.
- Special Notes:
  - Medicaid
    - This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.
    - Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.
    - The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health

problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.

 Service authorization requests must be accompanied by sufficient clinical records to support the request. Clinical records must be signed and dated by the requesting provider withing 60 days of the date of service requested.

#### **References:**

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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(2025). Retrieved Jan 21, 2025, from Hayes - a symplr company: <u>https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522autologous%2520myoblast%2522,%25</u> <u>22title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%252</u> 2:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522source

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(2025). Retrieved Jan 21, 2025, from Centers for Medicare and Medicaid Services: <u>https://www.cms.gov/medicare-coverage-database/search-</u> <u>results.aspx?keyword=autologous+cellular&keywordType=starts&areald=s53&docType=NCA,CAL,NCD,MEDCA</u> <u>C,TA,MCD,6,3,5,1,F,P&contractOption=all</u>

(2025). Retrieved Jan 21, 2025, from Google - Specialty Guideline Search: <u>https://www.google.com/search?q=professional+recommendation+autologous+myoblast+transplantation&safe=st</u> <u>rict&sca\_esv=8cc3bf1e6fd11b7c&rlz=1C1GCEJ\_enUS1093US1093&biw=1186&bih=521&sxsrf=ADLYWIL5B0JY</u> <u>RtpCzZNemwESOql\_M\_MfXQ%3A1737487478750&ei=dvSPZ66wLa2v5NoP7Z</u>

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NCD: Autologous Cellular Immunotherapy Treatment (110.22). (2011, Jun 30). Retrieved Jan 21, 2025, from Centers for Medicare and Medicaid Services: <u>https://www.cms.gov/medicare-coverage-</u> <u>database/view/ncd.aspx?ncdid=344&ncdver=1&keyword=autologous%20cellular&keywordType=starts&areald=s</u> <u>53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1</u>

Subchapter F - Biologics. (2025). Retrieved Jan 22, 2025, from Code of Federal Regulations: <u>https://www.ecfr.gov/current/title-21/chapter-l/subchapter-F</u> Young, M., & Dijksta, P. (2024, Dec 19). Biologic therapies for tendon and muscle injury. Retrieved Jan 21, 2025, from UpToDate: <u>https://www.uptodate.com/contents/biologic-therapies-for-tendon-and-muscle-injury?search=Autologous%20myoblast%20injection&source=search\_result&selectedTitle=1%7E150&usage\_type=edefault&display\_rank=1#H2827233597</u>

# Keywords:

SHP Autologous Myoblast and Muscle Cell Injection, SHP Medical 262, incontinence, stress urinary incontinence, fecal incontinence, bowel incontinence, oral incontinence, autologous myoblast transplantation